PATENT
Attorney Docket No. 044574-5003-02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

New DIVISIONAL Application of:	)	
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Yerramilli *et al.*	)	
	)	
Filed: December 6, 2001	)	
	)	
Prior Application No. 09/506,729	)	Prior Group Art Unit: 1636
	)	
Prior Filing Date: February 18, 2002	)	Prior Examiner: B. Loeb, Ph.D.
	)	
For: **A Process to Study Changes in Gene Expression in Granulocytic Cells**	)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

PRELIMINARY AMENDMENT

Prior to the examination of the above-identified application on the merits, please amend the application as follows:

IN THE CLAIMS:

Please cancel claims 1-13, without prejudice or disclaimer.

Please add the following new claims:

14. A method of identifying an agent that modulates a sterile inflammatory disease in a patient, comprising,

(a) isolating a granulocyte population from a patient with a sterile inflammatory disease;

(b) treating the granulocyte population with an agent;

(c) preparing a gene expression profile of said granulocyte population;

(d) comparing the gene expression profile of step (c) to at least one gene expression profile of an untreated granulocyte population from the subject known to have a sterile inflammatory disease, to identify agents that modulate a sterile inflammatory disease.

15. The method of claim 14, wherein the sterile inflammatory disease is selected from the group consisting of glomerulonephritis, psoriasis, rheumatoid arthritis, asthma, cardiac and renal reperfusion injury, thrombosis, adult respiratory distress syndrome, periodontal disease and inflammatory bowel disease.

16. The method of claim 15, wherein the inflammatory bowel disease is Crohn's disease or ulcerative colitis.

17. The method of claim 14, wherein the sterile inflammatory disease is glomerulonephritis.

18. The method of claim 14, wherein the granulocyte population is a neutrophil population, an eosinophil population, a basophil population, or a combined population of different granulocytic cells.

19. A method of identifying an agent that modulates a sterile inflammatory disease in a patient comprising,

(a) treating polymorphonuclear white blood cells from a patient known to have sterile inflammatory disease with an agent;

(b) preparing a gene expression profile from said polymorphonuclear white blood cells; and

(c) comparing the gene expression profile of step (b) to at least one gene expression profile of untreated polymorphonuclear white blood cells from the subject known to have a sterile inflammatory disease, to identify agents that modulate a sterile inflammatory disease.

20. The method of claim 19, wherein the sterile inflammatory disease is selected from the group consisting of glomerulonephritis, psoriasis, rheumatorid arthritis, asthma, cardiac and renal reperfusion injury, thrombosis, adult respiratory distress syndrome, periodontal disease and

inflammatory bowel disease.

21. The method of claim 19, wherein the inflammatory bowel disease is Crohn's disease or ulcerative colitis.

22. The method of claim 19, wherein the sterile inflammatory disease is glomerulonephritis.

23. The method of claim 19, wherein the polymorphonuclear white blood cells are neutrophils, eosinophils, basophils, or a combination of different polymorphonuclear white blood cells.

24. The method of claim 19, wherein the polymorphonuclear white blood cells are neutrophils.

25. A method of identifying an agent that modulates glomerulonephritis in a patient, comprising the steps of:

(a) isolating polymorphonuclear white blood cells from a patient with a glomerulonephritis;

(b) treating the polymorphonuclear white blood cells with an agent;

(c) isolating RNA from the isolated polymorphonuclear white blood cells;

(d) preparing a gene expression profile from the isolated RNA; and

(e) comparing the gene expression profile of step (d) to at least one gene expression profile of untreated polymorphonuclear white blood cells from the subject known to have glomerulonephritis to identify agents that modulate glomerulonephritis.

26. The method of claim 25, wherein the polymorphonuclear white blood cells are neutrophils, eosinophils, basophils, or a combination of different polymorphonuclear white blood cells.

27. The method of claim 25, wherein the polymorphonuclear white blood cells are neutrophils.

28. The method of claim 14, wherein the granulocyte population is from peripheral blood.

29. The method of claim 19, wherein the polymorphonuclear white blood cells are isolated from peripheral blood.

30. The method of claim 25, wherein the polymorphonuclear white blood cells are isolated from peripheral blood of the patient.

31. A method of any one of claims 14, 19 or 25. wherein the expression profile comprises the expression level of at least about 5 genes.

32. The method of any one of claims 14, 19 or 25, wherein the expression profile comprises the expression level of at least about 10 genes.

33. The method of any one of claims 14, 19 or 25, wherein the expression profile comprises the expression level of at least about 50 genes.

34. The method of claim any one of claims 14, 19 or 25, wherein the expression profile comprises the expression level of at least about 100 genes.

35. The method of claim any one of claims 14, 19 or 25, wherein the expression profile is prepared by hybridization of nucleic acids to nucleic acids immobilized on a solid substrate.

36. The method of claim 35, wherein the solid substrate is selected from the group consisting of nitrocellulose membrane, nylon membrane, silicon wafer, and borosilicate slide.

IN THE ABSTRACT

After page 68 of the specification, please insert the Abstract as attached.

REMARKS

I. Status of the Claims

Claims 1-13 have been canceled. Claims 14-36 have been added. Support for claims 14-36 can be found throughout the specification. For instance, the diseases or conditions recited in claims 15-17 and 20-22 are found on page 3, lines 23-27 and page 10, lines 21-26. Methods to identify agents that modulate sterile inflammatory diseases are described on page 7, lines 5-25 as well as in Example 6. The types of granulocytes recited in claims 18, 23, 24, 26, and 27 are described in the Definitions on page 10, lines 6-8. The isolation of granulocytes from peripheral blood as recited in claims 28-30 are described in the Examples. Example 7 provides a description of solid substrates as recited in claims 35-36. Applicants respectfully submit that no prohibited new matter has been added by this Amendment.

II. Conclusion

The Examiner is requested to telephone the undersigned if a discussion of any remaining issues would facilitate issuance of the claims.

EXCEPT for issue fees payable under 37 C.F.R. §1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. §' 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

This paragraph is intended to be a **CONSTRUCTIVE PETITION FOR EXTENSION OF TIME** in accordance with 37 C.F.R. § 1.136(a)(3).

Respectfully Submitted,

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By: 
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Date: December 6, 2001

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